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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,640	11/27/2001	Thomas George Gant	PC11042A	8096

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EXAMINER

SMALL, ANDREA D SOUZA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,640

Applicant(s)

GANT ET AL.

Examiner

Andrea D Small

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

I. Preliminary Matters:

- (a) Applicants response filed 11/07/2003 has been received and entered into the file.
- (b) Claims 1-37 are pending.

II. Remarks:

- (a) Issues regarding double patenting: Applicants have traversed this rejection by asserting three main points.

First, that under the rules of claim construction, claim terms are given their ordinary meaning as one skilled in the art would understand them unless it appears from the specification that the terms were used differently by the inventions, thus, since the term “pharmaceutically acceptable salts” are well-understood term of art and that one of ordinary skill would not have to refer to the specification to understand the meaning of the term.

The examiner agrees with the Applicant, however, in this instance, the specification *does* provide a definition for the term that is narrower than the ordinary meaning of the term. Column 11 of the ‘764 patent provides for the specific types of salts that are encompassed by the instant claims. Thus, looking to the definition of the terms used in the claims in the specification is permissible as indicated in *In re Boylan* and *In re Vogel*.

Second, that the examiner “is trying to import a limitation from the specification in the claims of the ‘764 patent”, which has been clearly prohibited by the courts. The Examiner respectfully disagrees. If the examiner were reading limitation of the specification into the claims, the rejection under debate would have been a statutory double patenting rejection rather than an *obvious-type* double patenting rejection. Portions of the specification which provide support for

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the present claims may also be examined and considered when address the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*. The '764 patent specification provides the obvious variants of pharmaceutically acceptable salts of the compounds claimed. Thus, the reading and examination of these obvious variants is proper.

Third, the list of salts outlined in the specification does not provide any teaching or suggestion in the '764 patent to lead one to make the particular claimed compounds. The examiner disagrees. There is ample motivation and suggestion provided in the '764 patent. Column 11, lines 38-50 of the patent provides for the obvious variations of the claimed invention, i.e., the pharmaceutically acceptable salts of the claimed compounds, especially those that are preferred. Thus, one of ordinary skill in the art would be motivated to make additional pharmaceutically acceptable salts of the compounds claimed in the '764 patent as the patent specifically indicates the preferred pharmaceutically acceptable salts embodiments of the compounds, consequently providing a reasonable expectation of success in the end utility of said compounds.

Therefore, the double patenting rejection is proper and maintained.

(b) The rejection under 35 USC 103(a): The statement under 35 USC 103(c) filed by Applicants has been found sufficient to overcome this rejection.

III. Maintained Rejections:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-37 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, compounds 1 and 2 and claims 10-23 of U.S. Patent No. 6,235,764. Although the conflicting claims are not identical, they are not patentably distinct from each other because

The instant claims are drawn to various salts of the compound 3-(4-bromo-2,6-difluorobenzyloxy-5-[3-(4-pyrrolidin-1-yl-butyl)-uriedo]-isothizole-4-carboxylic acid amide, pharmaceutical composition and method of using the same. The difference between that claimed instantly and the reference is that the instant claims claim specific salts of the compounds that are not claimed. However, the reference teaches that pharmaceutically acceptable salts of the compound may be made, see claim 10, and the reference lists various salt forms that can be made, see col. 11, lines 38-50. Therefore, one of ordinary skill in the art would be motivated to make additional salt forms of this known compounds with the specific suggestion and teaching that the reference provides that the claimed salt form can be made and provide a reasonable expectation of success in being employed for the same utility.

IV. Finality:

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

V. Contact Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrea D. Small, whose telephone number is (703) 305-0811. The examiner can normally be reached on Monday-Thursday from 8:30 AM - 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [Joseph.McKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

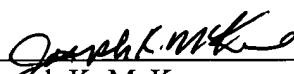
Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1234

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Andrea D. Small, Esq.
February 13, 2004



Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626
Technology Center 1